tled law, the jury, the trial court, and the Federal Circuit agreed.

REASONS FOR DENYING THE PETITION

I. THE FEDERAL CIRCUIT'S DECISION IN THIS CASE IS ENTIRELY CONSISTENT WITH CONTROLLING LAW.

In upholding the jury's verdict in this case, the Federal Circuit acknowledged that a patent applicant must disclose the best mode of carrying out his invention, which the panel described as "a mode of practicing his *claimed invention* that he considered to be better than any other."[17] Petitioner fundamentally misrepresents the panel's holding by asserting that the panel held that "there is no best mode violation unless the undisclosed mode goes to that *part of the claim* to which the invention (is said to be) directed . . . ."[18] Contrary to petitioner's argument, the panel did not distinguish among *elements* of the claimed inventions but, instead, properly distinguished between *entire trocar devices which incorporate the claimed inventions* and the *inventions claimed* in the three patents-in-suit:

> [A]n applicant is obliged to disclose nonclaimed elements necessary to the operation or carrying out of the invention to which the patent is directed. *See, e.g., Dana Corp.*, 860 F.2d at 418, 8 USPQ2d at 1695 (fluoride treatment "necessary to satisfactory performance of [the] seal"); *Chemcast*, 913 F.2d at 928, 16 USPQ2d at 1037. However, where the invention relates only to a part of, or one aspect of, a device, an applicant is not required to disclose a nonclaimed element *necessary to the operation of the*

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17 Pet. App. at 3a (emphasis supplied) (quoting *Chemcast Corp.*, 913 F.2d at 927-28).

18 Pet. at 13 (emphasis supplied).

> *overall device, but not necessary to the operation of the invention to which the patent is directed.*[19]

This distinction between a claimed invention and a broader device which merely includes the claimed invention is well established.[20] *Nothing* in the panel's decision departs from the established law that the "invention" to which a patent is directed is delineated by the patent claims, considered as a whole, rather than merely some portion of the claims.

Ironically, after falsely asserting that the panel erred in focusing on only part of the claimed inventions, *petitioner* argues that this Court should focus on *a single claim element*—the seal—in assesing whether the claims-in-suit satisfied the best mode requirement of 35 U.S.C. § 112 ¶ 1:

> each of the six asserted claims contains a trocar seal *element*. The seal *element* is therefore a *component of* each claimed combination. That being so, there is no escape under this Court's decisions in *Aro I* and the *Mercoid* cases from the legal conclusion that failure to disclose Parylene-C is a best mode violation, as it is necessary to the operation of the trocar seal *element* . . . of each asserted claim.[21]

This argument is squarely contrary to controlling law. Section 112 ¶ 1 requires that the patent disclose the best mode of "carrying out [the] *invention*," **not** an "*element* of the invention." Likewise, in *Aro*, on which petitioner purports to rely, this Court stated that "if anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant." [22]

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[19] Pet. App. at 4a (emphasis supplied).

[20] *See Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1579-80 (Fed. Cir. 1991).

[21] Pet. at 13-14 (emphasis supplied).

[22] 365 U.S. at 344; *see id.* at 345 (discussing *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 667 (1944); *Mercoid*

Petitioner's position impermissibly ignores the requirement that a court examine the "totality of elements" of the claim.

The decisions below are correct and completely in accord with governing patent law.

II. PETITIONER'S SPECULATION THAT THE FEDERAL CIRCUIT'S DECISION WILL CAUSE "CONFUSION" IS UNFOUNDED AND, IN ANY EVENT, PREMATURE.

Petitioner's forecast of confusion resulting from the Federal Circuit's decision in this case is based entirely on *petitioner's* interpretation of that decision—which is erroneous for all of the reasons set forth above. Courts following the panel's decision will simply apply the settled rules of best mode law: they will construe the claims at issue to determine the scope of the claimed invention, and then determine whether there is clear and convincing evidence that the patent failed to disclose the inventors' preferred mode for carrying out that invention at the time the patent application was filed. Contrary to petitioner's suggestion, the Federal Circuit's decision in this case creates no "new issue for patent litigation" and certainly does not "eliminate, in an unpredictable number of cases, the duty to comply" with the requirements of 35 U.S.C. § 112 ¶ 1.[23]

In any event, petitioner's prediction that the panel's decision "is impossible to administer" is entirely speculative, if not dead wrong. It is extremely unlikely that any district court would misconstrue the panel's decision in the way petitioner has. Even if that were to happen, however, the appropriate body to address that confusion in the first instance is the Federal Circuit, which petitioner acknowl-

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Corp. v. Minneapolis-Honeywell Regulator Co., 320 U.S. 680, 684 (1944)).

[23] Pet. at 9.

edges to be "[t]he country's principal patent court."[24] There is simply no reason for this Court to weigh in now.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for a writ of certiorari.

Respectfully submitted,

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[24] Pet. at 9.

APPENDICES

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APPENDIX A

Excerpts, Trial Testimony (By Deposition) of Inventor Donald L. Gadberry (April 22, 1997)

DIRECT EXAMINATION BY U.S. SURGICAL

[201] (Deposition reading resumed)

"Q. Why did Applied choose Parylene over Vydax?
A. I don't know. That wasn't my decision.
Q. Was that a decision, to your knowledge, that was made by Mr. Ritchart?
A. Yes.
Q. Did Mr. Cooper have any input into that decision to your knowledge?
A. I don't know."

(Deposition reading paused)

* * * *

[207] Q. At this time, were you considering using silicone on a septum seal?
A. Yes.
Q. Did you also test silicone?
A. I believe so.
Q. And again, silicone for the purpose of reducing friction on the seal?
A. Well, just for checking different material to see how it would work in comparison with C-flex.
Q. But you weren't intending the silicone to be a replacement for the Parylene coating, [208] correct?
A. We were considering it. If it worked, it would be used as a material. Whether it would be coated or not, I don't know.
Q. But you were looking at silicone as an alternative to C-flex?
A. A as a parallel path, yes.
Q. Page 52168—
A. Okay.

Q. —reflects additional of your observations regarding the Parylene coating?

A. Yes.

Q. This reflects additional testing that you were doing on the Parylene?

A. Well, I don't know if it reflects additional testing. I would have to read it to find that out.

Q. Please do that.

A. It looks like this indicates what we did with respect to trying out Parylene-N as compared to Parylene-C, and a rather rough enginering evaluation of the difference.

Q. Were you indicating on this page that you thought the Parylene-C coated samples were preferable to Parylene-N coated samples?

[209] A. I don't know if I came to any conclusion on here at all.

APPENDIX B

Excerpts, Trial Testimony of Inventor Mark A. Richart (April 23, 1997)

CROSS-EXAMINATION BY APPLIED MEDICAL

[209] Q. Now, Parylene-C, in order for Parylene-C to work, would you agree that you could not tolerate any portion of the Parylene flaking off[] during the insertion of an instrument, correct?

A. You couldn't tolerate flaking off, no.

Q. For a whole host of reasons, you couldn't tolerate having any Parylene flaking off during the insertion of an instrument; is that correct? I didn't mean—

A. You could not tolerate Parylene flaking off during insertion of an instrument.

Q. And you, therefore, wouldn't have and couldn't have commercially recommended the use of Parylene-C—you wouldn't in your job, I take it, until and unless you had resolved the problem of Parylene-C flaking off during the insertion of an instrument, correct?

A. Until we thought we had it under control, yes.

Q. And sir, you continued to have tests done with respect to Parylene-C until well after the issuance of the '737 Patent, did you not?

[210] A. I don't recall.

Q. Do you recall looking there when the '737 Patent issued? Do you still have that in front of you?

THE COURT: Let's just—there is no dispute about that. It's on the patent. It's May 11, '93, isn't it?

ATTORNEY NEAL: Yes.

THE COURT: All right, next question.

BY ATTORNEY NEAL:

Q. Would you turn back to your lab notebook, Plaintiff's Exhibit 124?

A. Okay. (Complied)

Q. Mr. Rodriguez has just pointed out, what I meant to ask you was the filing date of the '737 Patent, which is July 18, 1991, correct?

A. You are asking me about the filing date of the '737 Patent was July 18, '91?

Q. Yes.

A. Yes.

Q. Okay. And my question was, you continued to experiment with Parylene-C long after July 18, 1991, did you not?

A. I don't recall.

Q. And do you recall whether you had continuous [211] problems with Parylene cracking and falling off long after July 1991?

A. Well, in general we had problems with stopcocks, ripped seals and dirty Parylene sometimes, and in that regard we probably wrestled with it a little bit.

Q. Would you direct your attention now in exhibit, Defense Exhibit—I'm sorry, Plaintiff's Exhibit 124, which is your second lab notebook, and can you find a page that is dated 12/5/91, please?

A. (Complied) yes.

Q. And on page — does the page marked 12/5/91, report on the results of Parylene tests with Parylene coated seals.

A. Yes.

Q. And as of 12/5/91, does this indicate that there was—if you look in the Number 2, there is cracked Parylene?

A. Yes.

Q. And then below that there is an indication that Parylene flaked off easily when the C-flex is stretched?

A. Yes.

Q. And then under Number 4, it indicates Parylene flaked off easily when the C-flex stretched, correct?

A. I can see that.

Q. C-flex is the material that you were working with [212] at the time for the septum valve itself?

A. We were working with 5 Shore C-flex, and I believe, if we could go back and take a look at these part

numbers, at the time we were busily trying to test other forms of C-flex, and how well this C-flex adhered to that, this Parylene adhered to those forms of C-flex. So, we are looking at these different sorts of C-flex, higher durometer C-flex, and different forms.

Q. One of the problems with flaking, I take it, flaking Parylene would have a negative effect on friction and an even more negative effect on patients, if Parylene flaked off and went downstream into the patient during an operation; would you agree with that?

A. I agree with that.

Q. On March—can you look, finally, at the page in your book dated March 11, 1992?

A. (Complied) Okay.

Q. Do you have that page? It's is headed "Testing of ETO Units." Do you see that?

A. My March 11th says "Needs stainless rod 446."

Q. On March 11th, I am looking for a page that says "Testing of ETO units." There is a little drawing actually in the upper right-hand corner.

THE COURT: Do you have a Bates Number?

[213] ATTORNEY NEAL: This one does not have any Bates number on it. I apologize?

THE WITNESS: Lot Number 92B. Is that the one?

ATTORNEY NEAL: I think he's got it now, your Honor.

THE COURT: All right, proceed.

BY ATTORNEY NEAL:

Q. Sir, that page indicates that as of March 11th, 1992, you were still experimenting with and testing Parylene, does it not?

A. Yes.

Q. And this test performed as of March 11th, 1992, you were still experiencing cracking and flaking of Parylene-C, were you not?

A. Looks like we were experiencing cracking of the Parylene.

APPENDIX C

Excerpts, Trial Testimony of Inventor Charles C. Hart (April 16, 1997)

CROSS-EXAMINATION BY U.S. SURGICAL

[39] Q. Now, Mr. Hart, I would like to talk about the seals that are used in the Applied designs. Did Applied, in the manufacture of any of the prototypes or products that it attempted to commercialize, ever put any coatings on the seals that it used?

A. Yes, sir.

Q. And the purpose of putting a coating on the seal was to help reduce the amount of friction that might exist between [40] that seal and the instrument that might be inserted into the seal?

A. Yes, sir. Coatings were used throughout the trocar instruments. I don't remember picking up a trocar that didn't have some sort of lube on it.